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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

27752 7590 06/25/2003

THE PROCTER & GAMBLE COMPANY
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EXAMINER	
SHAREH, SHAHNAM J	
ART UNIT	**PAPER NUMBER**
1617	15

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/692,634	RENNIE ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 9, 2003 has been entered.

Claims 1-9, 20-30 are pending and are under consideration. All rejections of record are withdrawn in view of new grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gangadharan et al US Patent 5,643,582 in view of Szentmiklosi US Patent 5,244,880 and Davidson et al US Patent 6,080,783.

Gangadharan discloses compositions suitable for nasal application comprising a humectants such as 2-pyrrolidinone-5-carboxylic acid salts (2-pyrolidinone-5-carboxylic acid is the same as instantly claimed pyroglutamic acid), a moisturizing agent, a polymeric bioadhesive agent, ascorbyl palmitate, benzoic acid, a therapeutic agent and a pH modifying agent (see abstract, col 2, lines 50-67; col 4, lines 5-65; col 5, lines 20-30, 33-60; col 6, lines 6-56; col 10, line 50; col 13-14). Examiner points out that benzoic acid of Gangadharan is an organic acid with a pKa of 3.0 to about 5.0. In fact, the instant application acknowledges such fact (see instant specification, page 6, line 21, claim 5). Gangadharan's composition does not use pyroglutamic acid, rather, it contains salts of pyroglutamic acid instead of pyroglutamic acid. Gangadharan also fails to use zinc in his compositions

Szentimiklosi discloses topical compositions comprising pyroglutamic acid. Compositions of Szentimiklosi further contain topical ingredients such as an organic

acid, a mucoadhesive agent and even a propellant (examples 2-9). Szentimiklosi teaches that his aqueous solutions can be prepared conventionally in the form of oleaginous formulations such as ointments, creams, foams or emulsions (col 3, lines 37-41; col 2, lines 29-65; example 8). Szentimiklosi is also used to establish that pyroglutamic acid and its salts possess similar pharmaceutical and cosmetic characteristics and are viewed to be art recognized functional equivalents. Further, Examiner takes the position that topical compositions encompass nasal composition, because they are all viewed in the art as topical methods of delivery. Szentimiklosi does not explicitly teach nasal formulations of his compositions.

Davidson is used to show that Zinc metals such as zinc gluconate can be administered nasally (abstract. Specifically, Davidson teaches nasal compositions comprising zinc metal, a thickener, and other suitable carrier ingredients for treatment of cold. (see abstract, examples 1-6). Davidson's compositions do not contain pyrolgutamic acid.

With respect to the composition claims, Examiner states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, Applicant is informed that the recitation of "nasal composition" does not involve any unobvious difference between the structure of the claimed

composition and those of the cited references, because such limitations relates solely to the matter of use of the claimed composition. Accordingly, the manner or method in which such claimed compositions are to be utilized is not germane to the issue of patentability of the composition itself, because the structure provided by the reference possessed the capabilities requisite to meet the terms and function of the claims. Therefore, the mere recitation of "nasal compositions" does not involve an unobvious difference between the compositions of the prior art and those instantly claimed.

Moreover, the functional limitation of "providing a surface pH of the nasal cavity tissue from about 3.5-5.5" does not impart patentability over the cited references, because the combined teachings of the references meet all the elemental components of the claimed invention, and therefore, its functional characteristics as well.

It has been held that the selection of known material based on its suitability for its intended use supported a *prima facia* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Gangadharan's composition by substituting its pyroglutamic acid salts with pyroglutamic acid of Szentimiklosi, because they are art recognized functional equivalents. Further, the ordinary skill in the art would have been motivated to add zinc salts of Davidson to Gangadharan's composition because he would have had a reasonable expectation of success in improving its clinical benefits for nasal application.

The ordinary skill in the art would have had a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a

list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.,* 325 U.S. at 335, 65 USPQ at 301. Thus, since all elements of the instant claims are taught in the cited references combining them for their own intended use would have been *prima facia* obvious.

Finally, Examiner states that it would have been obvious to one of ordinary skill in the art at the time of invention to employ pyroglutamic acid and zinc metal combination for treating common cold because both compounds are conventionally employed for treating infectious conditions in topical compositions (see Szentimiklosi for pyroglutamic acid and Davidson for Zinc). Therefore, the ordinary skill in the art would have had a reasonable expectation in observing clinical benefits when zinc is combined with pyroglutamic acid in a topical composition.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner
Art Unit 1617

ss
June 20, 2003